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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,392	05/30/2001	Steffen Lav	NN-5595.210 US	7486
7590	05/05/2005		EXAMINER	
Patent Department Skadden, Arps, Slate, Meagher & Flom LLP Four Times Square New York, NY 10036-6522			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	
			DATE MAILED: 05/05/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,392	LAV ET AL.	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 February 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 11-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11-31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the application lacks support for the claimed recitations of “a lancer removably mounted in said housing” in claim 1 and “a second compartment adapted to removably receive and store a lancer” in claim 24. [Emphasis added] While claim language is viewed broadly and the specification is looked to in order to further understand the claims, the instant disclosure does not teach any part of the lancer that could be construed as “mounted in the housing” or “a second compartment on the housing to removably receive and store a lancer”.

In the Remarks section of the correspondence received on 3/14/2002, Applicant tries to assert that locking means 31 are a pair of hooks that are received in the housing. Locking means (31) are taught in the specification but are never further described to include hooks or any other structure. Additionally, the figures provide no further information regarding the locking means (31). The figures show element 31 as a quadrilateral shape, however one cannot tell if this structure extends from the lancer or is a recessed space (opening) that another member would

insert into. Furthermore, the quadrilateral shape could depict a “black box” element that depicts an entirely different intended structure.

Also, no reference to a compartment, or any similar language, that receives the lancer can be found in the specification. Additionally, the figures do not depict a compartment structure for receiving and storing the lancer. Conversely, the pictures more correctly show a concave portion on the lancer (surface with locking means 31: fig 3) that receives the housing (30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al (USPN 5,728,074). Castellano discloses a housing (400), a monitor (442) integrally disposed in the housing, a medication delivery pen (22: see fig 25c), and a lancer (424) removeably secured to the housing. See figure 25a and 19:18-20:39. Castellano fails to include the delivery pen being removably mounted in the housing.

However, at the time of the invention, it would have been obvious to make the pen removable from the housing. Making the pen removable is supported by the court and by common knowledge in the art.

The court has held that if making a component of a device removable were desired then it would be obvious to make it so for that reason. In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is “press fitted” and therefore not manually removable. The court held that “if it were considered desirable for any reason to obtain access to the end of [the prior art’s] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.”). See M.P.E.P. 2144.04. In the instant case, one would desire removing the pen of Castellano upon failure of the pen to function while the rest of the system was still usable with the desire to replace the pen.

Response to Arguments

Applicant's arguments filed 2/7/05 have been fully considered but they are not persuasive.

Applicant main argument is that even though the specification does not disclose the locking means as hooks, the locking means 31 can only be interpreted as hooks based on the drawings. Regardless of whether the locking means 31 are hooks or any other type of protuberance the instant specification still lacks support for the claims language of “mounted in”. The lack of support results in the fact that the instant written disclosure and figures are completely silent as to the portion of the housing that, for lack of a more precise word, accepts the locking means 31 of the lancet. The side of the housing that connects with the lancet is not described or shown in any fashion for one to make any assumptions as to the structure that connects with locking means 31. In order for the specification to support “mounted in” one

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would need to be able either see from the drawings or read in the written disclosure that this is actually the case. Finally, as stated in the above rejection, the disclosure provides more support for the housing being mounted in the lancet due to the concave nature of the wall of the lancet that connects with the housing.

Additionally, applicant did not address the rejection citing the lack of support for "a second compartment". It is assumed that applicant acquiesces to the fact that the instant disclosure does not provide support for this limitation.

In response to applicant's argument that there is no motivation in the reference itself for the 103 rejection above, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is found generally available to one of ordinary skill in the art. See rejection above for motivation statement.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *dsn.*
September 22, 2004



NICHOLAS D. LUCCHESI
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